Analysis of Formal Public Comments and Staff Recommendations

SUBTITLE 24 MARYLAND HEALTH CARE COMMISSION
10.24.05 RESEARCH WAIVER APPLICATIONS: ATLANTIC C-PORT STUDY OF NON-PRIMARY PCI – NOTICE OF PROPOSED ACTION

MARYLAND HEALTH CARE COMMISSION

September 20, 2007

Gail R. Wilensky, Ph.D.
Vice Chair

Rex W. Cowdry, M.D.
Executive Director

TABLE OF CONTENTS

I. INTRODUCTION

The Maryland Health Care Commission's Cardiac Surgery Chapter of the State Health Plan, COMAR 10.24.17, permits applications for a research waiver that would permit hospitals without on-site cardiac surgical backup to participate in a well-designed, peer-reviewed research study of the safety and efficacy of non-primary PCI in those hospitals. Since the Cardiac Surgery Chapter of the State Health Plan was adopted in 2004, the Commission has received two proposals to conduct research to assess the safety and effectiveness of non-primary PCI in Maryland hospitals without on-site cardiac surgery. Based, in part, on the guidance of its Research Proposal Review Committee, the Commission voted on April 19, 2007 to establish a waiver program to permit a limited number of hospitals to participate in a research project conducted by the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT).

To guide the submission of applications for research waivers, on May 10, 2007, the Commission released draft regulations for informal public comment, with comments due on May 25, 2007. The Commission received written comments from 17 organizations. After analyzing and responding to the informal comments, staff recommended certain changes to the draft regulations, which the Commission adopted as proposed permanent regulations at its June 21, 2007 meeting. A Notice of Proposed Action on the proposed regulations (COMAR 10.24.05) was published in the *Maryland Register* on Friday, August 3, 2007, with comments due on September 4, 2007.

By the close of the 30-day formal comment period on September 4, 2007, the Commission had received written comments on the proposed action from five organizations:

- Adventist HealthCare
- LifeBridge Health
- MedStar Health
- St. Joseph Medical Center
- University of Maryland Medical System

The remainder of this document summarizes the written comments received, and presents the staff analysis and recommendations. All written comments received on the proposed regulations (COMAR 10.24.05) are available for review on the Commission's website (http://mhcc.maryland.gov/) or by contacting the Center for Hospital Services, Maryland Health Care Commission, at 410-764-3232.

II. SUMMARY AND ANALYSIS OF PUBLIC COMMENTS

.02 Purpose.

A. ***This Chapter establishes a one-time process by which a licensed acute general hospital without on-site cardiac surgery services may seek a waiver from the requirements of COMAR 10.24.17.04E, Policy 5.0, and be permitted to provide non-primary PCI services as part of the C-PORT study to assess the safety and efficacy of providing non-primary PCI services for certain patient groups without on-site cardiac surgery backup, as provided in COMAR 10.24.17.04E, Policy 5.3.***

Summary of Comments

University of Maryland Medical System (UMMS) requests further clarification of the expression "one-time process." Will applications for waivers to participate in the C-PORT research study be accepted only once during the course of the study? If a hospital is unsuccessful in its initial application for an npPCI waiver, is it precluded from reapplying? Similarly, if a hospital granted a waiver subsequently relinquishes it, would another hospital be allowed to apply for a waiver? Will all six of the available waivers be granted when the program begins, or will some number of waivers be set aside for future participation by hospitals in Western Maryland and/or on the Eastern Shore? It would seem that engaging the maximum number of hospitals as early as possible would assure the timely recruitment of patients and expedite the successful conclusion of the study.

Staff Analysis and Recommendation

The C-PORT investigators project that the study will be completed by January 2010. As of August 15, 2007, there were 31 participating hospitals and nearly 4,000 patients have been enrolled in the study. The Commission anticipates receiving applications for npPCI waivers on one or two occasions. The only hospitals that currently have two-year waivers are located in the Metropolitan Baltimore and Metropolitan Washington regional service areas. The Commission will publish the schedule for receipt of applications from hospitals with two-year waivers in the *Maryland Register*. The number of applications, outcome of the review process, and status of approved but not yet operational pPCI programs in Western Maryland will determine the number and distribution of npPCI waiver study sites.

Hospitals in the two metropolitan service areas will have one opportunity to apply for an npPCI waiver; a hospital in either of the two non-metropolitan regional service areas will be able to apply when it reaches the volume and other requirements found in .03B(2). A hospital granted a waiver to participate in the C-PORT study that subsequently loses or relinquishes its waiver will not be permitted to reapply for a waiver. Similarly, the Commission will not reopen the application process in the event that a hospital loses or relinquishes its waiver.

The C-PORT study is, by definition, a research study, and its success is predicated on enrolling patients from hospitals that represent the full spectrum of hospitals without on-site

cardiac surgical services. While the outcome of the study may ultimately assist in guiding health care planning in Maryland, staff believes that it is prudent to limit the number of hospitals that are allowed to participate in the study. Consequently, COMAR 10.24.05 provides for the granting of npPCI waivers to no more than six Maryland hospitals that do not have on-site cardiac surgery.

Staff does not recommend any changes to this provision.

C. ***The Commission may grant a waiver from Policy 5.0 of COMAR 10.24.17.04E for no more than six (6) hospitals without on-site cardiac surgery to perform non-primary PCI as part of the C-PORT study.***

Summary of Comments

MedStar Health (MedStar) suggests that the number of waivers to be issued should be allocated based on regional service area with one waiver allotted to each region, stating that the proposed regulation does not reflect Commission policy on geographic distribution of the waivers. MedStar notes that there is nothing in the proposed regulation that prevents the Commission from granting six waivers to hospitals in only one region, or that requires an even distribution of the six waivers. The Commission and the staff have previously expressed the view that a primary reason for allowing expansion of PCI services is to improve the ability of rural hospitals to perform PCI. It therefore follows that the majority of waiver sites for primary PCI should be granted to rural hospitals. Moreover, for the Metropolitan Baltimore and Metropolitan Washington regional service areas where there is much better access to PCI services than in either the Western Maryland or Eastern Shore regions, the regulations should require additional and substantial justification in order to warrant the granting of more than one waiver. There must be a compelling justification for exposing patients to additional risk with no corresponding clinical benefit.

University of Maryland Medical System suggests that, by limiting the number of waivers to six or fewer, the Commission is being too restrictive relative to the overall size of the study. UMMS believes that any hospital that is successfully meeting the criteria of the pPCI waiver program and providing quality clinical outcomes should not be precluded from participating in the study, particularly if such a hospital is likely to enroll large numbers of patients in the study. Reserving one or more waivers for hospitals in non-metropolitan service areas further restricts the participation of qualified metropolitan area hospitals.

Staff Analysis and Recommendation

In the context of this research study, the Commission seeks to provide for participation by hospitals in non-metropolitan regions, a consideration central to objectives of the study, while assuring that participation by Maryland hospitals will contribute substantively to the outcome of the study.

By providing for participation by up to six hospitals without on-site cardiac surgery, the regulation assures that Maryland hospitals and patients will be well represented in the

study. Currently, there are no hospitals in the Western Maryland or Eastern Shore regional service areas that offer pPCI services under the State's pPCI waiver program. Two Western Maryland hospitals are expected to begin offering pPCI services early in 2008. When considering applications by hospitals that have two-year pPCI waivers, the Commission will determine how many of the six waivers to award in the metropolitan regional service areas, and, consequently, how many waivers will remain for non-metropolitan areas.

Given the study's projected end date, the Commission anticipates that at least one hospital in the Western Maryland regional service area may meet the application and review criteria in a sufficiently timely manner and, thus, be able to apply for a pPCI waiver that would allow it to contribute to the research project. This does not mean that any hospital, wherever located, will receive an npPCI waiver. The review criteria include a number of measures related to a hospital's provision of pPCI services under COMAR 10.24.17; npPCI waivers will be granted only to the most qualified hospitals.

Staff does not recommend any changes to this provision.

.03 Waiver Application.

B. ***Eligibility to File Application.***

(1) A hospital without on-site cardiac surgery in the Metropolitan Baltimore or Metropolitan Washington regional service area may file an application for a waiver to perform non-primary PCI services within the C-PORT study if, at the time of application, the hospital has a 2-year waiver to perform primary PCI.

(2) A hospital without on-site cardiac surgery in the Eastern Shore or Western Maryland regional service area may file an application for a waiver to perform non-primary PCI services within the C-PORT study if, at the time of application, the hospital has a waiver to perform primary PCI, has provided PCI services for at least six months, and has completed a minimum of 18 primary PCI procedures in a six-month period.

Summary of Comments

MedStar Health proposes an additional eligibility requirement for hospitals in the Metropolitan Baltimore and Metropolitan Washington regional service areas, namely that the applicant hospital be at least five miles from an existing open heart surgery center. Many of the hospitals in the Baltimore and Washington regions are located very near existing tertiary hospitals. These hospitals typically draw interventional cardiologists from the same pool of interventionalists that serve nearby tertiary centers. MedStar believes that allowing npPCI at these centers will not significantly improve access to pPCI services. Additional competition for the same pool of scarce staff and physician resources will increase costs substantially. The five-mile requirement, therefore, should help improve geographic access, and may help to minimize the cost impact on programs that share the same staff.

University of Maryland Medical System asks whether the Commission would consider historical patient volume and outcome data from a hospital that had previously provided pPCI services, but was no longer doing so.

Staff Analysis and Recommendation

MedStar proposes adding an additional eligibility requirement that a hospital located in either metropolitan planning region could not seek a waiver if it is located less than five miles from the nearest existing cardiac surgery hospital. Staff believes that, because the quality of a metropolitan area hospital's pPCI program is independent of its location, setting a minimum distance requirement with respect to the locations of existing cardiac surgery hospitals would potentially preclude well-qualified hospitals from applying for an npPCI waiver.

In response to the question posed by UMMS, Staff notes that an application for an npPCI waiver may be submitted only by a hospital that has been granted a pPCI waiver and is actively providing those services in accord with the provisions of COMAR 10.24.17. Hospitals that previously provided pPCI services, but are no longer doing so would need to apply for and be granted a pPCI waiver and accrue the required experience before applying for an npPCI waiver as described in this provision.

Staff does not recommend any changes to this provision.

.04 Review of Applications

A. *Review Criteria.*

Summary of Comments

Adventist HealthCare (Adventist) suggests that, in addition to the criteria established by the proposed regulations, the Commission consider additional factors when reviewing applications for an npPCI waiver: hospitals not currently operating a PCI program should be required to demonstrate their ability to attract and sustain support from the interventional cardiac community and their patients; hospitals currently operating a PCI program should be required to provide the volume of procedures performed and the length of time the program has sustained that volume as evidence of support by the cardiology community.

Staff Analysis and Recommendation

The proposed regulations specify that only those hospitals that have an active pPCI program as provided for by COMAR 10.24.17 are eligible to apply for a waiver to perform npPCI as part of the C-PORT research project. Patient volume is one of the factors that the Commission will consider when reviewing npPCI waiver applications as provided in .04A(3)(e), which requires assessment of the applicant's performance under its pPCI waiver. Staff does not recommend any changes to the regulations to address the issues raised by the commenter.

(1) An applicant must meet the study site inclusion criteria established in the Atlantic C-PORT research study protocol.

(2) The applicant must document that it will satisfy the following requirements:

(a) For institutional Resources:

(i) An applicant shall provide a patient prioritization plan that guarantees that a patient who requires primary PCI for STEMI is given immediate preference for care in the cardiac catheterization laboratory.

(ii) An applicant shall submit a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution; and

(iii) An applicant shall provide documentation that it has an advanced cardiac support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for non-primary PCI patient transport by the applicant;.

(b) For physician resources, an applicant shall document that it has or will recruit adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists who:

(i) Meet the requirements in the C-PORT study research protocol and in COMAR 10.24.17, Table A-1;

(ii) Can be available on-site within thirty minutes when on call; and

(iii) Agree to abide by the Device Selection Criteria in the C-PORT study protocol defined in its Manual of Operations;

Summary of Comments

MedStar Health reiterates its concern that a hospital with only three interventional cardiologists will have no latitude with regard to illness, vacation, or scheduling conflicts, and suggests that requiring a minimum of four or five interventional cardiologists would be more appropriate in order to be able to provide the required 24/7 coverage. In addition, staff shortages and increased competition for scarce staff are likely to result from expanding npPCI services. MedStar notes that increasing the minimum number of required interventionalists will aggravate this situation, but believes that requiring only three interventionalists will lead to insufficient coverage.

Staff Analysis and Recommendation

Hospitals providing pPCI services under the Commission's current waiver program that could apply for an npPCI waiver understand and appreciate that they have assumed the burden of securing sufficient staff to provide those services. Failure to do so places the hospital at risk of losing its waiver. Some existing pPCI waiver hospitals employ staffing levels consistent with those recommended by MedStar, while others have been and are continuing to staff their pPCI programs with three interventionalists. Staff does not recommend changes to this provision.

(c) For minimum volumes, an applicant shall document that it will meet and maintain a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver annually; and

Summary of Comments

LifeBridge Health (LifeBridge) and **St. Joseph Medical Center** (St. Joseph) note that the draft version of COMAR 10.24.05 required hospitals granted an npPCI waiver to perform 200 procedures annually. The proposed regulations, as published in the *Maryland Register*, require 100 procedures during the first year and 200 during the second year of its waiver. Because there is clear evidence that the number of PCI procedures performed by a hospital is directly related to the quality of the service, reducing the number of required procedures may increase patient risk. Indeed, the American College of Cardiology (ACC) and the American Heart Association (AHA) Guidelines for PCI recommend, ideally, a minimum institutional volume of 400 procedures annually. Both hospitals recommend that the Commission establish, at the least, an annual minimum of 200 procedures

University of Maryland Medical Systems suggests that the wording of this provision is unclear. Does volume refer to only pPCI procedures, only npPCI procedures, or both?

Staff Analysis and Recommendation

LifeBridge and St. Joseph consider requiring npPCI waiver hospitals to perform a minimum of 100 procedures during the first year to be too lenient with respect to the ACC/AHA Guidelines for PCI, which recommend an ideal 400 case minimum. Staff notes that the Guidelines acknowledge that achieving a 400-case minimum may be difficult at low volume hospitals. The ACC/AHA therefore recommends a minimum volume of 200 cases at such hospitals.

The Commission adopted a 100 case minimum for the first year of a waiver in recognition of the difficulties likely to be encountered in establishing a new npPCI research program. Because Maryland hospitals applying for an npPCI waiver must possess a pPCI waiver and meet specific volume requirements under COMAR 10.24.17, Table A-1, those selected to participate in the study are likely to meet or exceed the first year minimum. Staff recognizes and endorses the ACC/AHA Guidelines, but given the potential importance of the

study to informing health policy in Maryland and nationally, does not recommend more stringent institutional volume requirements.

The Commission's volume requirements under COMAR 10.24.05 are based on the combined total of pPCI and npPCI procedures.

Staff does not recommend any changes regarding the number of procedures required by this provision.

Staff recommends revising .04A(2)(c) to read: For minimum volumes, an applicant shall document that it will meet and maintain a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver [~~annually~~]; and

(d) Patient Follow-up. An applicant must commit to meet and maintain a patient follow-up rate of 98% for patients enrolled in the C-PORT study.

(3) In determining whether to grant a waiver application, the Commission may consider appropriate factors, including:

Summary of Comments

MedStar Health suggests that the Commission be required to consider whether granting a waiver application will: 1) have an adverse impact on existing npPCl providers; 2) raise the cost of health care in the State; and 3) cause or contribute to a shortage of the highly trained staff necessary to run catheterization laboratories. In addition, before granting any waivers, the Commission should be required to consider whether the C-PORT study, based on its historical performance, is likely to produce reliable results.

MedStar notes that the C-PORT study has been enrolling patients for a year and a half. Data for this period (which represents almost 2/3 of the projected 28-month study) already indicates that the study may not produce reliable results. For instance, the annualized enrollment rate is approximately 127 patients per hospital, which is below the study's anticipated annual recruitment of 200 patients per hospital. In addition, the study was originally predicted to last for 28 months, with an end date in mid-2008. It is now clear that the project will run much longer, resulting in significant additional costs. However, there is no indication of where the necessary additional funding will come from.

In his recommendation, Commission Executive Director Dr. Cowdry noted that the study is likely to cost around $4 million and that the ability to meet the costs of the study is a concern, and that the study's funding should be closely monitored. MedStar presumes that hospitals that have been participating in the study since early 2006 have already made their two-year contributions to the study and assumes that those fees were most likely based on the study's original cost projection of $34,000 per year and not on the revised cost projection of $52,500 per year. It should be a simple matter to determine how much of the projected $4 million in funding the study actually has received to date.

Staff Analysis and Recommendation

MedStar expresses concern about the effect of the npPCI waiver program on existing npPCI providers, on health care costs, and on the availability of trained and accomplished catheterization laboratory staff. Staff observes that the research waiver program is of limited duration, and that the term of the study is a function of the number of participating hospitals and the rate of patient enrollment at those hospitals. Maryland hospitals that participate in the study will need to establish new npPCI programs and attract patients to those programs in the absence of any assurances that the programs will continue beyond the end of the study. Staff considers it unlikely that individually or in aggregate the research programs will demonstrably adversely affect existing npPCI centers.

Because the costs of the study are borne by hospitals participating in the study, a hospital's decision to apply for a waiver to participate in the study is a business decision reflecting the applicant's willingness to fund the study. The C-PORT study is designed to determine if there are cost differences in hospitals with and without on-site cardiac surgery and to characterize those differences.

Current waiver hospitals must have sufficient staff to make primary PCI available 24 hours per day, seven days per week. It remains to be seen whether the initiation of npPCI services at up to six Maryland hospitals under the research waiver program will affect the availability of qualified staff. Given that npPCI services are scheduled and not provided emergently, and that the potential pool of patients is finite it seems reasonable that the overall demand for interventional cardiologists and associated staff will remain unchanged. In many instances, hospitals with a pPCI waiver are already sharing interventional cardiologists with hospitals that have on-site cardiac surgery. Staff acknowledges the possibility that the opening of new npPCI programs may affect staffing patterns, but in the absence of evidence, does not find this concern to be convincing.

MedStar recommends that, during the application review process, the Commission be required to review the status of the overall study, particularly with regard to funding. The proposed regulations provide, at .05A, that an npPCI waiver expires if the Commission determines the research study is unlikely to produce reliable results to guide public policy. The Commission intends to closely monitor the overall progress of the C-PORT study, as well as the performance of Maryland hospitals participating in the study. Study participation by Maryland hospitals is predicated on the ongoing progress of the overall study in meeting its objectives.

Staff does not recommend changes to this provision.

(a) An applicant's potential to improve the geographic distribution of cardiovascular services;

Summary of Comments

University of Maryland Medical System observes that the purpose of the C-PORT study is to determine the safety and efficacy of npPCI procedures performed in hospitals without on-site cardiac surgery, yet the proposed regulations seem to dilute that focus by trying to assure geographic access to the participants in the study. Aligning the study to include an assessment of geographic access could lead to a faulty design that is unlikely to be beneficial to either assessment. UMMS contends that geographic access to care should not be a factor in determining the appropriateness of an award of an npPCI waiver to any hospital. UMMS encourages the Commission to focus on the primary outcome of the study, i.e., safety and efficacy, and not to introduce extraneous issues such as geographic diversification and access representation. Hospital selection should be based on prior demonstration of solid outcomes under the Commission's pPCI waiver program and the ability to contribute to the objectives of the npPCI study.

Staff Analysis and Recommendation

The Commission's interest in including hospitals from various regional service areas within the State is not to introduce a new variable into the study protocol. Rather, if the study is to assess whether npPCI services can be safely and effectively provided by hospitals without on-site cardiac surgery, many of which are located in non-metropolitan areas throughout the U.S., ensuring that hospitals in Maryland's non-metropolitan areas have an opportunity to participate would help the study achieve its objective. The Staff does not recommend any changes to this section of the proposed regulations.

(b) An applicant's potential to increase access to PCI services for minorities and medically underserved populations;

(c) An applicant's ability and commitment to serve as a site for conducting research;

(d) An applicant's demonstration of successful and timely acquisition of followup data on primary PCI patients; and

(e) An applicant's current performance under its primary PCI waiver.

Summary of Comments

Adventist HealthCare observes that the selection of hospitals to receive waivers to perform npPCI should be based the performance history of the applicant's primary PCI program. Criteria that might be considered include mean door-to-balloon time, complication rates, the ability to initiate measures to treat complications in an expedited manner, and quality outcome measures that meet or exceed national averages based on publicly available data. Patients should have confidence that they are being treated by a high volume program that has a proven track record, and by an established cardiology team that produces quality outcomes.

MedStar Health notes that because a hospital's experience and performance under the Commission's pPCI waiver program will be used, in part, to determine which hospitals will be granted a waiver to provide npPCI services as part of the C-PORT study, the Commission should strictly enforce the pPCl program requirements. MedStar Health states that the Commission has already demonstrated that it will not enforce the pPCI criteria, and this has potential implications for the quality of care in the npPCI programs. In 2006, the Commission granted several hospitals in the Metropolitan Baltimore and Metropolitan Washington regional service areas conditional one-year waivers to perform pPCI. Although many of these hospitals had been performing pPCI for several years as part of the original C-PORT study, the Commission did not grant these hospitals two-year waivers because of their failure to meet one or more of the criteria established under the pPCI waiver program. For example, some had not met patient volume requirements or their door-to-balloon times were excessively long. Nevertheless, the waivers for some of these hospitals subsequently were extended, even though they did not meet the criteria after a year of treating patients. If these criteria are not important to the quality of care, they are meaningless and should be dropped from the regulations. Otherwise, the regulations should be enforced by the Commission, and waivers should not be renewed for any hospital that does not meet the criteria.

University of Maryland Medical System questions how the Commission intends to weigh a hospital's performance under its pPCI waiver against the other review criteria – the potential of the hospital's program to improve geographic access and to increase access to PCI services by minorities and medically underserved populations, the applicant's ability to serve as a research site, and its ability to successfully obtain follow-up data in a timely manner. Hospitals that have several years experience, have consistently supplied reliable research data, and are currently performing well under the pPCI waiver criteria should be given greater consideration than those without the benefit of such history and experience. A waiver ought to be granted to hospitals that are active participants in C-PORT I with continued performance improvements, quality outcomes, and committed physicians, staff and administrators. Such factors should be given greater consideration than those related to geographic access or ability to increase services to underserved populations.

Staff Analysis and Recommendation

Maryland hospitals without on-site cardiac surgery that provide pPCI services do so under a waiver program established in COMAR 10.24.17. Waiver hospitals submit a variety of volume, performance, and outcome data to the Maryland ST-segment Elevation Myocardial Infarction (STEMI) Registry. The Commission reviews these data quarterly and the results and trends are used to inform its decisions. These data will form the basis of the pPCI performance assessments for a hospital that applies for an npPCI waiver. The additional review criteria to which UMMS refers will provide the Commission with additional insights by which to gauge the npPCI waiver applications.

Staff does not recommend changes to this provision.

B. ***The Commission staff shall prepare a staff report and recommendation on a waiver application for consideration by the Commission.***

.05 Waiver Term.

Summary of Comments

MedStar Health recognizes the various scenarios identified in COMAR 10.24.05 under which an npPCI waiver might end, but believes the proposed regulations could do a much better job of anticipating and planning for the end of the npPCI waiver program. Will waiver hospitals be expected to follow current policy that prohibits those without on-site cardiac surgery from providing npPCI services? Is that policy subject to change at the time the npPCI waiver program ends? The Commission should consider an additional rule addressing how a waiver hospital will transition from performing npPCI services pursuant to the limited research waiver to an interim period in which final policies are developed. Because the proposed regulations are vague on this point, the Commission risks misleading hospitals into making investment decisions regarding equipment and personnel based on a belief or expectation that their npPCI service is likely a permanent one.

The Commission also should be well aware of the potential difficulty it will face at the end of the C-PORT study. At that time, it would be appropriate to require the waiver hospitals to stop performing npPCI. However, once the infrastructure, i.e., the designated space, staff, equipment and physician referral patterns, is in place, those hospitals would naturally want to find a way to continue the service to their patients. The Commission has no precedent for requiring a hospital to discontinue a service. MedStar states that the Commission has shown a reluctance to terminate an existing service if that service does not meet the Commission's own established quality of care criteria, even though it clearly has the authority to do so. Thus it is imperative that the Commission establish this framework in advance of the implementation of COMAR 10.24.05.

MedStar suggests that language be added to the proposed regulations stating that under no condition will a waiver be renewed or extended to permit a continuation of npPCI services. Further, the regulations should require that the waiver hospital cease operation of its npPCI services at a specified time following the end of the study or termination of the waiver. This will assure that providers know what to expect at the study's conclusion. If analysis of the study data eventually results in a change in policy, the Commission will then have a clear and level playing field on which to begin a new ballgame.

Staff Analysis and Recommendation

Regulation .05A lists factors associated with the overall study that can result in expiration of npPCI waivers, with .05A(1) providing that the waiver expires two years from the date on which it was issued. Further, as provided for in regulation .06, certain conditions related to a hospital’s performance would trigger the relinquishment of its waiver. A hospital considering applying for an npPCI waiver should anticipate that its program will close at the

time the waiver ends. Staff does not recommend changes to this provision of the proposed regulations.

A. ***A waiver to perform non-primary PCI issued by the Commission will expire on the earlier of:***

(1) Two years from the date on which the waiver was first issued;

(2) The date patient accrual into the C-PORT study ends;

(3) A finding made by the Commission that the C-PORT study is not accruing patients at an acceptable rate; or

(4) A finding by the Commission that the C-PORT study is unlikely to produce reliable results to guide public policy.

Summary of Comments

MedStar Health suggests that npPCI waivers should be granted for a maximum period of one year, not two years, so that the Commission may do a better job of monitoring whether the applicant is meeting the volume and other requirements of the study and the regulations. Granting waivers for one year would be consistent with the current process of granting an initial, one-year waiver to hospitals seeking to provide pPCI services. This would also establish a definitive timeframe and process for re-evaluation of the study's overall experience, and a continuing assessment of the likelihood that the study will produce reliable results.

Staff Analysis and Recommendation

As with the pPCI waiver program, the Commission will monitor hospital performance and study progress on an ongoing basis. Staff believes that a two-year waiver is appropriate in a time-limited research study and does not recommend any changes to this provision.

.06 Conditions for Maintaining a Waiver.

A. ***A hospital with a waiver to perform non-primary PCI shall notify the Commission in writing of the occurrence of any of the following:***

(1) The hospital performs non-primary PCI on a patient not enrolled in the C-PORT study;

(2) The hospital's primary PCI waiver expires, is relinquished, or is withdrawn;

(3) The hospital fails to notify the Commission within three business days of death or coronary bypass surgery experienced by a patient participating in the C-PORT study;

(4) The hospital fails to perform a minimum of 100 PCI procedures by the first year anniversary of its non-primary PCI waiver or 200 PCI procedures by the second anniversary of its non-primary PCI waiver; or

(5) The hospital fails to meet and maintain the criteria for participation in the C-PORT study or its participation in the C-PORT study ends for any reason.

Summary of Comments

LifeBridge Health, **St. Joseph Medical Center**, and **University of Maryland Medical System** reiterate their comments regarding provision .04A(2)(c) that it is inappropriate to require that a hospital granted an npPCI waiver perform a minimum of 100 total PCI procedures during the first year of its waiver. The ACC and AHA recommend that hospitals perform a minimum of 400 procedures annually.

Staff Analysis and Recommendation

As discussed regarding section .04A(2)(c), Staff does not recommend changing the number of procedures required by this provision.

Staff recommends revising .06A for clarity to read:

A. A hospital with a waiver to perform non-primary PCI shall notify the Commission <u>within 3 business days</u> in writing of the occurrence of any of the following:
. . .
(3) The hospital fails to notify the Commission [within 3 business days] of death or coronary artery bypass surgery experienced by a patient participating in the C-PORT study;

(4) The hospital fails to perform a minimum of 100 PCI procedures by the first year anniversary of its non-primary PCI waiver;

<u>(5) The hospital fails to perform a minimum of</u> 200 PCI procedures [by] <u>during</u> the second [anniversary] <u>year</u> of its non-primary PCI waiver; or

<u>(6)</u> The hospital fails to meet and maintain the criteria for participation in the C-PORT study or its participation in the C-PORT study ends for any reason.

Other Comments

Summary of Comments

MedStar Health suggests that interested parties and participating entities should be permitted in npPCI application reviews, and that the Commission should be required to consider potential adverse impacts on existing providers and the cost implications of granting a waiver to allow a hospital to participate in the study. The proposed regulations provide that the Commission may extend a waiver beyond the currently proposed two-year period.

Because the study's lead researcher has predicted that the study may last twice as long as was initially projected it is possible that the waivers may be extended well beyond two years. MedStar states that this, coupled with the study's 1:3 randomization scheme (i.e., for every 4 patients, 3 who ordinarily would have been diverted to a nearby heart center will remain at the waiver hospital) could result in significant adverse impacts on existing providers, as well as increased costs to payors, despite the temporary nature of the waiver.

MedStar also recommends that the Commission require documentation from each applicant of the projected and/or actual incremental costs for equipment, transportation, and staffing, including all costs related to contracts and other arrangements associated with physician coverage that are attributable to participation in the study. Selection of certain waiver sites will have a definite negative impact on costs to the health system and on existing heart centers. Pulling volume from a strong heart center to bolster volume at a nearby community hospital will only serve to decrease overall quality of care in the State by creating a pool of mediocre providers as opposed to having a select number of centers of excellence. Evidence establishes that, due to economies of scale, the cost to perform npPCl is significantly greater ($6,084 per procedure in 2002) at a low volume hospital than at high volume hospitals. Finally, there are a finite number of highly qualified interventional cardiologists and staff necessary for performing PCIs and running catheterization labs. Broadening the field of hospitals providing such services will only create bidding wars for these physicians and staff. Because future public policy development would only benefit from this type of data, the Commission should collect it now.

MedStar further suggests that the Commission should require documentation that each participating facility has a sound plan in place to secure informed consent from potential study participants, ensuring that participants understand the goals of the study, the risk of participating in the study, and are advised that less risky treatment alternatives are available to them. Also, given that preferences are contemplated in the selection criteria for those programs that expand access to minority populations, many that are currently underserved, it is acutely important that the study population is balanced in terms of representation and not overly represented by minorities. Specific efforts should be made to ensure that minority populations, many whom may not have personal primary care providers, be informed of the options for care available to them other than through the study.

Staff Analysis and Recommendation

MedStar raises a number of points regarding the proposed regulations. It requests that the regulations permit interested parties and participating entities to review and comment on applications, as in Certificate of Need ("CON") reviews. The npPCI waiver program is unique and quite distinct from the CON program. With these proposed regulations, the Commission will establish an application process for a limited number of hospitals to participate in a research study for a limited period of time. The Commission will monitor the C-PORT study overall, as well as the performance of participating hospitals in Maryland. If the Commission finds that the study is not accruing patients at an acceptable rate, or that the study is unlikely to produce reliable results to guide public policy, the Commission will halt the npPCI waiver program. Because of the limited scope of the waiver program, i.e., no more

than six hospitals will be permitted to participate and the time-limited duration of the study, staff does not recommend any changes to the proposed regulations to address this issue.

MedStar also suggests that npPCI waiver applicants be required to provide information about all costs associated with participation in the study. Staff appreciates that a hospital must commit significant resources to participate in the study, and that a hospital's decision to incur those costs must be based on its own economic analysis. Staff also notes that information on the costs of performing npPCI in participating hospitals will be collected as part of the C-PORT study. The Commission will review these data over the course of the study. Staff does not recommend any changes to the proposed regulations to address this issue.

MedStar expresses concern about the informed consent process at participating hospitals and whether patients will be provided with adequate, understandable information upon which to base their decision regarding participation in the study. In response to comments from the Commission's Research Proposal Review Committee, the C-PORT group made changes to the study's informed consent protocols that were subsequently approved by the Institutional Review Board of the Johns Hopkins Medical Institutions. This material is provided to all participating hospitals and serves as a template for investigators at each hospital to develop specific informed consent documents and protocols appropriate for the patient population served by that hospital. In all cases, the institutional review board at each participating hospital is responsible for reviewing and approving its own consent documents and procedures. Staff does not recommend making changes in the proposed regulations to address this issue.

General Comments

Adventist HealthCare, which operates hospitals with and without on-site cardiac surgery services, strongly supports the proposed regulations for permitting hospitals without on-site cardiac surgery to participate in the C-PORT research study of non-primary PCI (npPCI). **University of Maryland Medical System** (UMMS), representing University of Maryland Medical Center, Baltimore Washington Medical Center, and Shore Health System, endorses the expansion of npPCI services through community hospital participation in the research study. Both Adventist and UMMS offer specific comments intended to further enhance the Commission's waiver program.

LifeBridge Health operates hospitals with and without on-site cardiac surgery, and believes that the risks to patients participating in the C-PORT study are not outweighed by the benefits of the study. Moreover, because the proposed regulations establish a low institutional volume requirement during the first year of study participation, the risk to patients is likely to be further increased. With one exception, LifeBridge incorporates by reference all comments set forth in a letter dated May 24, 2007 from Warren A. Green to the Commission. The letter can be accessed at http://mhcc.maryland.gov/ hospital_services/specialservices/cardiovascular/comar102405pubcomm/lifebridgehlth.pdf. LifeBridge acknowledges that the proposed regulations adequately address its earlier

recommendation that the Commission be required to consider certain factors when reviewing applications for a waiver to perform npPCI.

MedStar Health, writing on behalf of Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, and Union Memorial Hospital, objects to the C-PORT study on ethical grounds and for reasons outlined below in the context of specific provisions of COMAR 10.24.05. MedStar anticipates that its specific suggestions will result in regulations that will better achieve high volumes, cost effectiveness, and improvement in geographic access if adopted by the Commission. However, MedStar believes that the study should not go forward in Maryland.

St. Joseph Medical Center believes that the risks to subjects participating in the C-PORT study are not outweighed by the benefits. These concerns coalesce around the expectation that at least some participating hospitals will be unable to achieve patient volumes associated with high quality patient care. St. Joseph addresses this issue in its specific comments.

Staff Recommendation, COMAR 10.24.05

The Staff recommends that the proposed regulations, incorporating the indicated non-substantive changes (shown as boxed text), be adopted by the Commission as final regulations.